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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/319,156	11/02/1999	GLAUCIA PARANHOS-BACCALA	103514	2490

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[REDACTED] EXAMINER

PARKIN, JEFFREY S

ART UNIT	PAPER NUMBER
1648	20

DATE MAILED: 12/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/319,156	PARANHOS-BACCALA ET AL.	
	Examiner	Art Unit	
	Jeffrey S. Parkin, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 03 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 16 July 2001.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-26 is/are pending in the application.

4a) Of the above claim(s) 2-6, 10-13 and 16-26 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1,7-9,14 and 15 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ .
2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>6, 7</u> .	6) <input type="checkbox"/> Other: _____ .

Detailed Office Action***Status of the Claims***

1. Applicants' election with traverse of Group I in paper no. 18 is acknowledged. Applicants incorrectly referred to the election of the env gene as a species election. No such species restriction requirement was set forth. Applicants are directed to the lack of unity notice set forth in the last Office action (paper no. 9) wherein it was clearly stated that: **In addition to the groups identified *supra*, applicants are required to identify and elect only those nucleotide sequences corresponding to a single and specific structural (i.e., gag, pol, or env) and regulatory region (i.e., LTR) of the viral genome.** This was not a species election requirement but rather an indication that nucleic acids encoding various viral structural and regulatory gene products are considered independent and distinct inventions. These disparate sequences lack a special technical feature because each of the identified nucleic acids will have a unique structure and function thereby necessitating separate searches. Applicants traverse and submit that the subject matter is closely related and would be covered by a single search. This argument is not deemed to be persuasive for the reasons of record previously set forth and as discussed *supra*. The claims lack a special technical feature as evidenced by the fact that the various groups identified are directed toward structurally and functionally different products (i.e., nucleic acids, primers, and proteins), compositions (i.e., diagnostic, therapeutic), and single method of use. Each of the identified sequences is derived from a different region of the retroviral genome and will contain a unique structure and function (i.e., the Gag proteins form the virion capsid, the Pol proteins contain enzymatic functions required for reverse transcription and integration, and the Env proteins are required for viral entry).

Moreover, the claimed invention also fails to make a contribution over the prior art as set forth in the ISA Chapter I search report which identified X and Y references. Accordingly, **the requirement is still deemed to be proper and is therefore made FINAL**. Claims 5 2-6, 10-13, and 16-26 are withdrawn from further consideration by the examiner, pursuant to 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention.

35 U.S.C. § 112, Second Paragraph

10 2. Claims 1, 7-9, 14, and 15 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The reference to "nucleic material" in claims 1 and 7-9 is vague and indefinite since the precise structural characteristics of said material are not readily manifest. Appropriate amendment of the claim language is required 15 (i.e., An isolated and purified nucleic acid comprising ...).

20 3. The reference to "at least 50%, and preferentially at least 70%" in claims 1, 9, 14, and 15 is vague and indefinite since the precise metes and bounds of the patent protection desired cannot be ascertained. Applicants are advised that a broad range or limitation followed by linking terms (e.g., preferably, maybe, for instance, especially) together with a narrow range or limitation 25 that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 U.S.P.Q.2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by 30 "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to

whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 U.S.P.Q. 74 (Bd. App. 1961); *Ex parte Hall*, 83 U.S.P.Q. 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 U.S.P.Q. 481 (Bd. App. 1949).

4. The reference to a nucleotide sequence "identical or equivalent" to SEQ ID NO.: 9 in claim 7 is confusing since the precise structural characteristics of the claimed nucleic acid are not readily manifest. Applicants may wish to amend the claim language to simply recite a nucleotide sequence having SEQ ID NO.: 9.

5. The reference to "sequences equivalent to" in claims 1, 14, and 15 are vague and indefinite since the precise structural characteristics of these sequences are not clearly set forth.

6. The reference to a gene which begins in one SEQ ID NO. and ends in a different SEQ ID NO. in claim 8 is confusing. Applicants should clearly identify the nucleotide sequence of the claimed region. For instance, an isolated and purified nucleic acid comprising SEQ ID No.: X.

35 U.S.C. § 112, First Paragraph

7. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1, 7-9, 14, and 15 are rejected under 35 U.S.C. § 112,

first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *In re Rasmussen*, 650 F.2d 1212, 211 U.S.P.Q. 323 (C.C.P.A. 1981). *In re Wertheim*, 541 F.2d 257, 191 U.S.P.Q. 90 (C.C.P.A. 1976). To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, e.g., *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at 1563, 19 U.S.P.Q.2d at 1116. The issue raised in this application is whether the original application provides adequate support for the broadly claimed genus of nucleic acids (e.g., equivalent sequences, sequences with a certain degree of homology, and fragments thereof). An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997). The claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the biomolecule of interest. *In re Bell*, 991 F.2d 781, 26 U.S.P.Q.2d 1529 (Fed. Cir. 1993). *In re Deuel*, 51 F.3d

1552, 34 U.S.P.Q.2d 1210 (Fed. Cir. 1995). A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed
5 process. See, e.g., *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571, 39 U.S.P.Q.2d 1895, 1905 (Fed. Cir. 1995). The court noted in this decision that a "laundry list" disclosure of every possible moiety does not constitute a written description of every species in a genus because it would not reasonably lead those skilled in the art
10 to any particular species.

An applicant may show possession of an invention by disclosure of drawings or structural chemical formulas that are sufficiently detailed to show that applicant was in possession of the claimed invention as a whole. An applicant may also show that an invention
15 is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that applicant was in possession of the claimed invention, i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed
20 correlation between function and structure, or some combination of such characteristics. For some biomolecules, examples of identifying characteristics include a nucleotide or amino acid sequence, chemical structure, binding affinity, binding specificity, and molecular weight. The written description
25 requirement may be satisfied through disclosure of function and minimal structure when there is a well-established correlation between structure and function. Without such a correlation, the capability to recognize or understand the structure from the mere recitation of function and minimal structure is highly unlikely.
30 In the latter case, disclosure of function alone is little more than a wish for possession; it does not satisfy the written description requirement. *Regents of the University of California*

v. Eli Lilly, 119 F.3d 1559, 1566, 43 U.S.P.Q.2d 1398, 1404, 1406 (Fed. Cir. 1997), cert. denied, 523 U.S. 1089 (1998). In re Wilder, 736 F.2d 1516, 1521, 222 U.S.P.Q. 369, 372-3 (Fed. Cir. 1984). Factors to be considered in determining whether there is sufficient evidence of possession include the level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention.

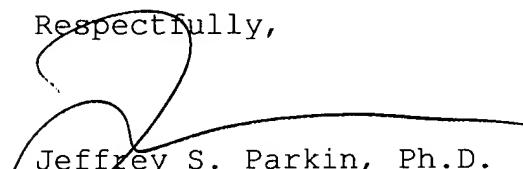
The specification describes the isolation and characterization of a novel human retrovirus that may be associated with multiple sclerosis. A molecular clone was obtained and the purported nucleotide sequence of the env gene ascertained. Thus, the skilled artisan would reasonably conclude that applicants were in possession of those particular clones containing SEQ ID NOs.: 6, 9, and 12. Appropriately drafted claim language directed toward these embodiments would be acceptable. However, the broadly recited claim language directed toward fragments, equivalents, and homologous sequences is unacceptable. Upon perusing the specification, nothing would lead the skilled artisan to any one of these particular sequences. None of these sequences are described in any detail. Accordingly, the skilled artisan would reasonably claim that applicants were not in possession of all these other sundry sequences.

9. Correspondence related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Official communications should be directed toward one of the following Group 1600 fax numbers: (703) 308-4242 or (703) 305-3014. Informal communications may be submitted directly to the Examiner through the following fax number: (703) 308-4426. Applicants are encouraged to notify the Examiner prior to the submission of such documents to facilitate

their expeditious processing and entry.

5 10 Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (703) 308-2227. The examiner can normally be reached Monday through Thursday from 8:30 AM to 6:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisors, James Housel or Laurie Scheiner, can be reached at (703) 308-4027 or (703) 308-1122, respectively. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

Respectfully,


Jeffrey S. Parkin, Ph.D.
Patent Examiner
Art Unit 1648

13 December, 2002